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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,144	03/25/2004	Robert Costa	03-284-E	7397

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EXAMINER

HALVORSON, MARK

ART UNIT PAPER NUMBER

1642

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,144	COSTA ET AL.	
	Examiner	Art Unit	
	Mark Halvorson	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 4-7 and 12-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 8-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/15/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicants election with traverse of Group II is acknowledged. Applicant's species elections of (a) malignant tumor cell and (b) liver cell are acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the restriction has been maintained. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Claims 1-49 are pending in the application and Claims 4-7, 12-49 have been withdrawn from further consideration by the examiner under 37 C.F.R. 1.142(b) as being drawn to non-elected inventions. Claims 1-3, 8-11 are currently under prosecution.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §119 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional

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application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application Nos. 60/457,257, 60/474,075 and 60/513,809, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Particularly, claim 11 is not supported by the prior-filed application because the disclosure of a polypeptide having an amino acid sequence as set forth in SEQ ID NO:10 is not supported in the prior-filed application US Patent Application NOs. 60/457,257, 60/474,075, 60/513,809, 60/540,691, and 60/549,211. Specifically, Patent Application NOs: 60/457,257, 60/474,075, 60/513,809, 60/540,691, and 60/549,211 do not disclose SEQ ID NO:10. Thus, claim 11 is hereby assigned the priority date of **March 25, 2004**, the filing date of the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3, 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the

steps. See MPEP § 2172.01. The omitted step is the active step that results in the inhibition of FoxM1M activity in the tumor cell. Moving the active step of claim 11 to the base claim, claim 1, may obviate this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 8, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Sherr et al (US Patent No. 5,723,313, issued March 3, 1998).

The claims are drawn to a method for inhibiting proliferation of a tumor cell by inhibiting FoxM1B activity, wherein FoxM1B activity is inhibited by causing FoxM1B protein to localize in the cytoplasm of a tumor cell, wherein FoxM1B activity is inhibited by preventing FoxM1B nuclear localization, wherein the tumor cell is a malignant tumor cell, wherein FoxM1B activity is inhibited by contacting the cell with a peptide having an amino acid sequence of SEQ ID NO:10.

Sherr et al disclose a method for using a peptide, ARF-p19, that comprises SEQ ID NO:10 (see Result 1, Sequence Search) or synthetic oligopeptides of ARF-p19 to inhibit growth of cancer cells (see column 19, lines 52-57). While Sherr et al do not explicitly disclose that the ARF-p19 inhibits FoxM1B activity by preventing

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FoxM1B nuclear localization and causing FoxM1B polypeptide to localize to the cytoplasm, Sherr et al's ARF-p19 peptide would inherently possess the ability to preventing FoxM1B nuclear localization and causing FoxM1B polypeptide to localize to the cytoplasm because these are functions carried out by the ARF-p19 polypeptide, as evidenced by Kalinichenko et al (see page 841, columns 1 and 2, Genes Devel 18:830-850, 2005).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherr et al in view of Laes et al (Cancer Genet Cytogenet 117:118-124, 2000).

The claims are drawn to a method for inhibiting proliferation of an epithelial liver tumor cell by contacting the cell with a peptide having an amino acid sequence of SEQ ID NO:10.

Sherr et al is described supra.

Sherr et al does not specifically teach tumor cells of epithelial liver cell origin.

Laes et al teaches that p19-ARF was missing or mutated in the majority of rodent hepatoma cell lines tested (see Table 3).

One of ordinary skill in the art would have been motivated to apply Laes et al's teaching that the tumor suppressor protein, p19-ARF, is missing or mutated in hepatoma cell lines to Sherr et al's method of treating cancer with p19-ARF in order to treat liver carcinomas with p19-ARF. It would have been prima facie obvious to one of ordinary skill in the art to use Scherr et al's p19-ARF peptide to treat Laes et al's hepatocellular carcinomas.

Summary

6. No claims allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571)

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272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson, PhD
Patent Examiner
571-272-6539


MISOOK YU
PRIMARY EXAMINER

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